

the licensed practitioner or discontinuing use of the drug product.

(5) The heading, “How should I take (name of drug)?” followed by information on the proper use of the drug product, such as:

(i) A statement stressing the importance of adhering to the dosing instructions, if this is particularly important;

(ii) A statement describing any special instructions on how to administer the drug product, if they are important to the drug’s safety or effectiveness;

(iii) A statement of what patients should do in case of overdose of the drug product; and

(iv) A statement of what patients should do if they miss taking a scheduled dose(s) of the drug product, where there are data to support the advice, and where the wrong behavior could cause harm or lack of effect.

(6) The heading “What should I avoid while taking (name of drug)?” followed by a statement or statements of specific, important precautions patients should take to ensure proper use of the drug, including:

(i) A statement that identifies activities (such as driving or sunbathing), and drugs, foods, or other substances (such as tobacco or alcohol) that patients should avoid when using the medication;

(ii) A statement of the risks to mothers and fetuses from the use of the drug during pregnancy, if specific, important risks are known;

(iii) A statement of the risks of the drug product to nursing infants, if specific, important risks are known;

(iv) A statement about pediatric risks, if the drug product has specific hazards associated with its use in pediatric patients;

(v) A statement about geriatric risks, if the drug product has specific hazards associated with its use in geriatric patients; and

(vi) A statement of special precautions, if any, that apply to the safe and effective use of the drug product in other identifiable patient populations.

(7) The heading, “What are the possible or reasonably likely side effects (name of drug)?” followed by:

(i) A statement of the adverse reactions reasonably likely to be caused by

the drug product that are serious or occur frequently.

(ii) A statement of the risk, if there is one, of patients’ developing dependence on the drug product.

(8) General information about the safe and effective use of prescription drug products, including:

(i) The verbatim statement that “Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide” followed by a statement that patients should ask health professionals about any concerns, and a reference to the availability of professional labeling;

(ii) A statement that the drug product should not be used for a condition other than that for which it is prescribed, or given to other persons;

(iii) The name and place of business of the manufacturer, packer, or distributor of a drug product that is not also a biological product, or the name and place of business of the manufacturer or distributor of a drug product that is also a biological product, and in any case the name and place of business of the dispenser of the product may also be included; and

(iv) The date, identified as such, of the most recent revision of the Medication Guide placed immediately after the last section.

(9) Additional headings and sub-headings may be interspersed throughout the Medication Guide, if appropriate.

#### **§ 208.24 Distributing and dispensing a Medication Guide.**

(a) The manufacturer of a drug product for which a Medication Guide is required under this part shall obtain FDA approval of the Medication Guide before the Medication Guide may be distributed.

(b) Each manufacturer who ships a container of drug product for which a Medication Guide is required under this part is responsible for ensuring that Medication Guides are available for distribution to patients by either:

(1) Providing Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to

permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product; or

(2) Providing the means to produce Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product.

(c) Each distributor or packer that receives Medication Guides, or the means to produce Medication Guides, from a manufacturer under paragraph (b) of this section shall provide those Medication Guides, or the means to produce Medication Guides, to each authorized dispenser to whom it ships a container of drug product.

(d) The label of each container or package, where the container label is too small, of drug product for which a Medication Guide is required under this part shall instruct the authorized dispenser to provide a Medication Guide to each patient to whom the drug product is dispensed, and shall state how the Medication Guide is provided. These statements shall appear on the label in a prominent and conspicuous manner.

(e) Each authorized dispenser of a prescription drug product for which a Medication Guide is required under this part shall, when the product is dispensed to a patient (or to a patient's agent), provide a Medication Guide directly to each patient (or to the patient's agent) unless an exemption applies under § 208.26.

(f) An authorized dispenser or wholesaler is not subject to section 510 of the Federal Food, Drug, and Cosmetic Act, which requires the registration of producers of drugs and the listing of drugs in commercial distribution, solely because of an act performed by the authorized dispenser or wholesaler under this part.

**§ 208.26 Exemptions and deferrals.**

(a) FDA on its own initiative, or in response to a written request from an applicant, may exempt or defer any Medication Guide content or format requirement, except those requirements in § 208.20 (a)(2) and (a)(6), on the basis that the requirement is inapplicable,

unnecessary, or contrary to patients' best interests. Requests from applicants should be submitted to the director of the FDA division responsible for reviewing the marketing application for the drug product, or for a biological product, to the application division in the office with product responsibility.

(b) If the licensed practitioner who prescribes a drug product subject to this part determines that it is not in a particular patient's best interest to receive a Medication Guide because of significant concerns about the effect of a Medication Guide, the licensed practitioner may direct that the Medication Guide not be provided to the particular patient. However, the authorized dispenser of a prescription drug product subject to this part shall provide a Medication Guide to any patient who requests information when the drug product is dispensed regardless of any such direction by the licensed practitioner.

**PART 210—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL**

Sec.

210.1 Status of current good manufacturing practice regulations.

210.2 Applicability of current good manufacturing practice regulations.

210.3 Definitions.

AUTHORITY: 21 U.S.C. 321, 351, 352, 355, 360b, 371, 374.

SOURCE: 43 FR 45076, Sept. 29, 1978, unless otherwise noted.

**§ 210.1 Status of current good manufacturing practice regulations.**

(a) The regulations set forth in this part and in parts 211 through 226 of this chapter contain the minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.